
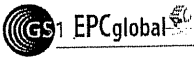


California Board of Pharmacy


State of Pedigree and EPC/RFID Standards

September 28, 2006



Agenda

- Standards Progress
- Serialization and Tagging Progress
- Pedigree Prototype event

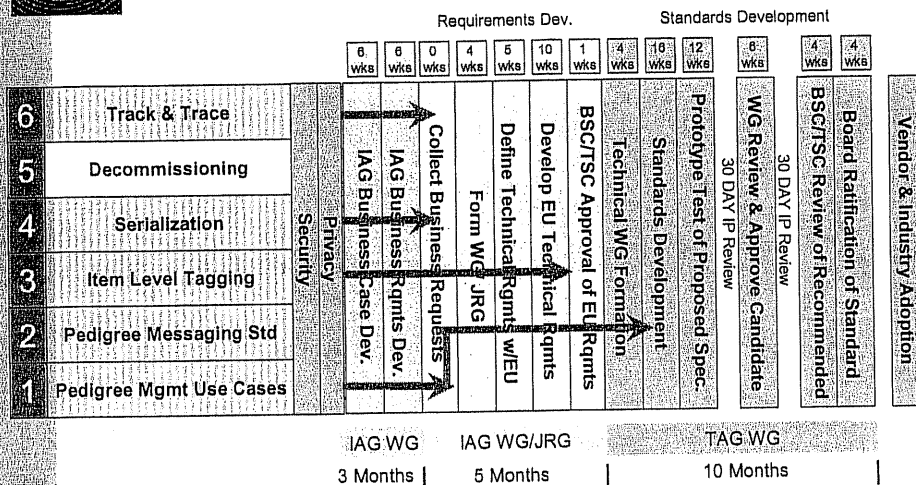


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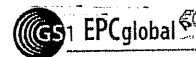


Standards Update

Last Report

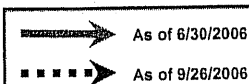
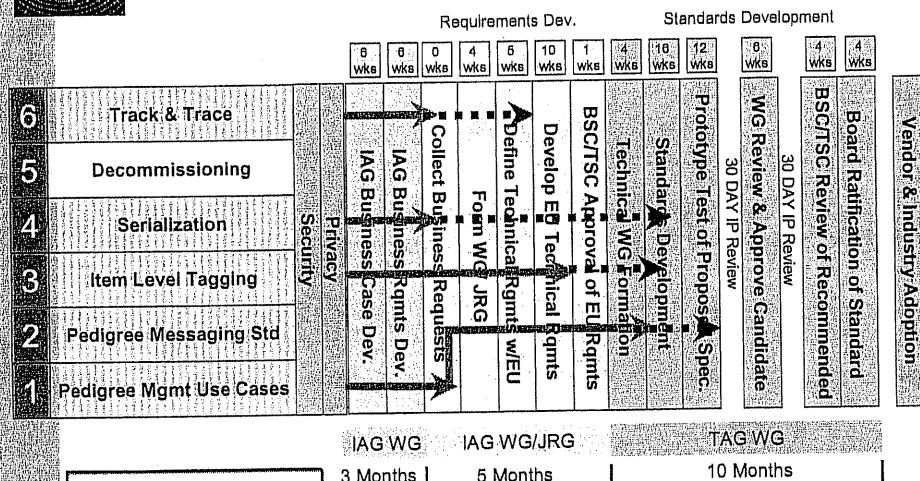


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Standards Update

As of 9/26/2006



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Standards Update

As of 9/26/2006

6	Track & Trace
5	Decommissioning
4	Serialization
3	Item Level Tagging
2	Pedigree Messaging Std
1	Pedigree Mgmt Use Cases

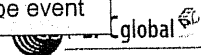
• Technical Requirements under way

• 2 GS1 standards identified as options
• May need 1 new standard for EPC that does not contain NDC
• Work with Industry Adoption WG and Industry Associations to establish direction

• Working group meeting this week to decide on tag feature alternatives for future EPCglobal HF standard (3qtr 2007)

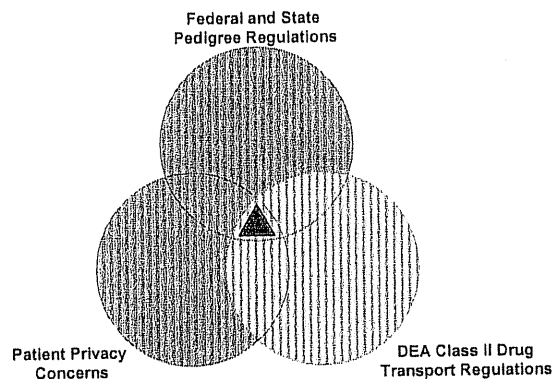
• Completed Prototype event

5

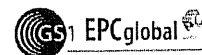


Understanding Serialization & Tagging Options

Regulatory and privacy



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Understanding Serialization & Tagging Options

Regulatory and privacy based requirements

FDA

- HHS PDMA Dec 2006
- Allows for Normal Distribution Rules
- Pro EPC/RFID

Florida

- Requires Pedigrees on all drugs Jun 2006
- Allows for Normal Distribution Rules
- Serialization not required
- Authenticate item before receipt

California

- Requires Pedigrees on all Drugs (starts w/ Manuf)
- 2009
- Serialization Required
- Authenticate item before receipt

DEA

- Sent letter to DEA
- Agreed to meet with us, scheduling meeting w/DEA

Manufacturers & Retail Pharmacies

- Concerns that patients receive tagged drugs before infrastructure is in place
- Concerns of Single Drug manufacturers

Requirements

Serialization at Item level

RFID

(Bar Code would require opening of each case on loading dock)

Tag Data Standard

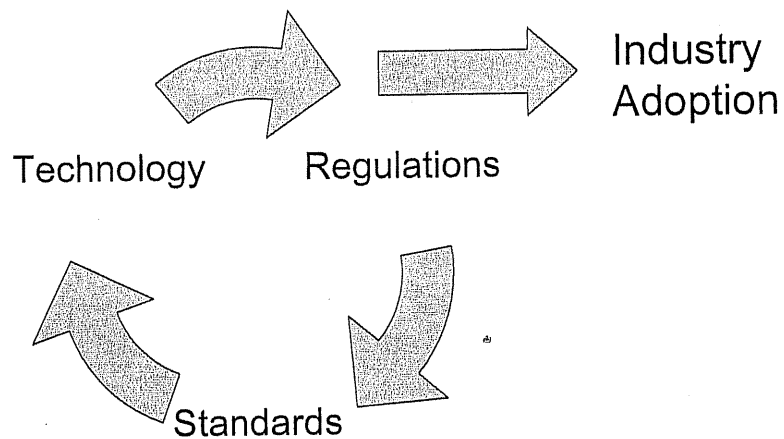
(No Product ID on Class II drugs)

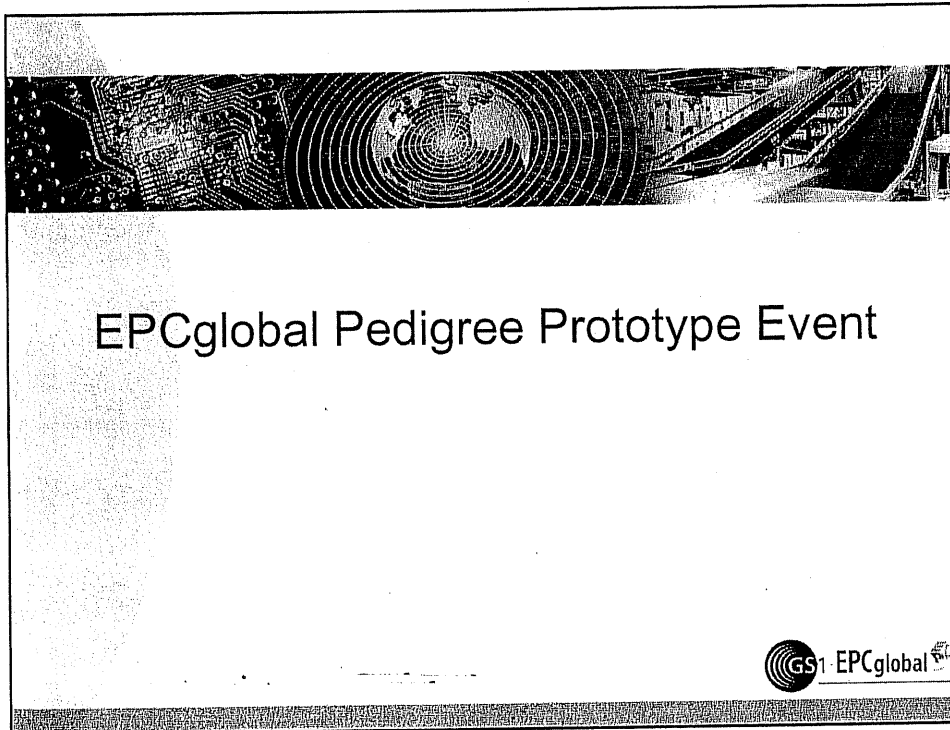
Tag Data Standard

(Temporarily, no Manager number on sensitive drugs)

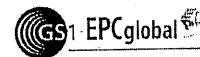


Interdependencies





EPCglobal Pedigree Prototype Event



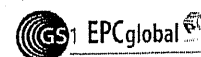
EPCglobal Pedigree Prototype Event Purpose and Format

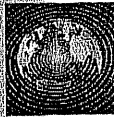
Purpose

- To test the Last Call Working Draft version of the standard
- To ensure that different parties would interpret the standard in the same manner

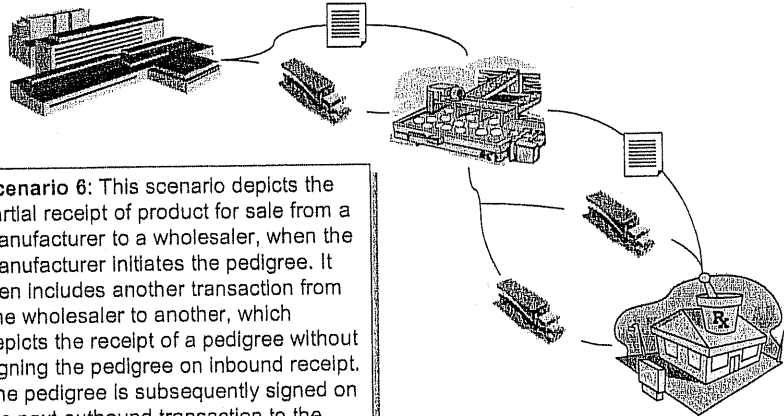
Format

- Six companies were given seven of the most challenging scenarios and test data to create Pedigrees against
- Their Pedigrees were compared, line by line, with the expected outcome from the standard
- 42 Pedigrees in total were tested





EPCglobal Pedigree Prototype Event Sample Scenario



Scenario 6: This scenario depicts the partial receipt of product for sale from a manufacturer to a wholesaler, when the manufacturer initiates the pedigree. It then includes another transaction from one wholesaler to another, which depicts the receipt of a pedigree without signing the pedigree on inbound receipt. The pedigree is subsequently signed on the next outbound transaction to the retail pharmacy.



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EPCglobal Pedigree Prototype Event Participating companies

Participants

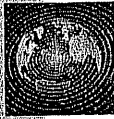
- Axway
- Cognizant
- Raining Data
- RFXcel
- SupplyScape
- VeriSign

Observers

- Accenture
- Cardinal Health
- EPCglobal
- Johnson & Johnson
- Tibco



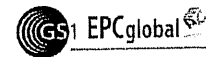
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EPCglobal Pedigree Prototype Event Outcome

- No Normative changes to the Standard
- List of explanatory changes to the Standard
- List of changes to the Guideline document
- An additional guideline scenario to the Guideline document

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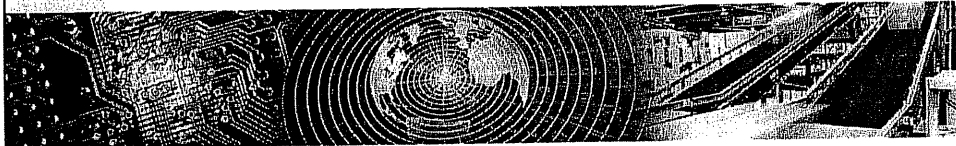


Next Steps


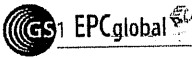
- Walk Board of Pharmacy through Pedigree scenarios
- Host workshop for Regulators from States with electronic pedigree bills
- Industry Adoption WG formed
 - Working with Industry Associations on Serialization & Item Level Tagging issues
- Upcoming events:
 - EPCglobal US Conference
 - NACDS/HDMA RFID Conference
 - Ongoing work on
 - Serialization
 - Item Level Tagging
 - Track and Trace
 - Building alignment w/In GS1 Organization
- Provide regular status updates to CA BoP

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Questions?



Additional Slides





EPCglobal Pedigree Prototype Event Scenarios

- **Scenario 1:** This scenario depicts the pedigree flow for the sale of a serialized product from a manufacturer to a wholesaler, when the manufacturer initiates the pedigree. The wholesaler then sells and ships one of the product items to a pharmacy DC.
- **Scenario 2:** This scenario depicts the sale of a non-serialized product from a wholesaler to a retail pharmacy DC, when no pedigree is provided by the manufacturer and the wholesaler initiates the pedigree.
- **Scenario 3:** This scenario depicts the sale from a wholesaler to a retail pharmacy DC, when a paper pedigree is provided by the manufacturer and the wholesaler initiates the pedigree.
- **Scenario 4:** The pedigree flow is described for a sale from a repacker to a wholesaler, where the repacker initiates the pedigree for a repackaged item. The repack pedigree contains the pedigree for the source product used to create the repack products
- **Scenario 5:** This scenario depicts the kitting of several products and the subsequent sale from a kit manufacturer to a wholesaler.
- **Scenario 6:** This scenario depicts the partial receipt of product for sale from a manufacturer to a wholesaler, when the manufacturer initiates the pedigree. It then includes another transaction from one wholesaler to another, which depicts the receipt of a pedigree without signing the pedigree on inbound receipt. The pedigree is subsequently signed on the next outbound transaction to the retail pharmacy.
- **Scenario 7:** This scenario depicts the pedigree flow for the sale of a non-serialized product from a manufacturer to a wholesaler, when the wholesaler initiates the pedigree. The wholesaler then sells and ships the product to a pharmacy DC, then the pharmacy DC returns the product to the wholesaler. Then the wholesaler sells and ships the product to another pharmacy DC. This pharmacy DC also returns the product to the wholesaler.



Understanding Serialization & Tagging Options Proposed Serialization Alternatives

Coding Scheme	Description	Level
#1 [Name TBD]	<ul style="list-style-type: none"> - DEA requirement that may not be fully addressed by existing GS1 standards - Entirely new schema for GS1 (similar to SSCC and GIAI tag formats) - 96-bit encoding - Manager Code - No Product Code - Larger capacity serial number than SSCC - Could be fully ser. w/ Manager Code of Issuing Auth. - Could apply to controlled substances 	<ul style="list-style-type: none"> - Item - Case - Pallet (option)
#2 SGTIN96	<ul style="list-style-type: none"> - Serialized Global Trade Identification Number - Existing and in use schema for GS1 - Contains Manager Code - Contains Product Code 	<ul style="list-style-type: none"> - Item - Case - Pallet
#3 N-National Code Support when companies are ready to apply RFID tags and ship to these countries	<ul style="list-style-type: none"> - For non-GS1 code requirements - Structure follows national code's own structure; e.g. Bolln, Vignette, etc. - May or may not include Product Code - If GSIN/SGTIN is not sufficient - Goal is to have as few of these as possible 	<ul style="list-style-type: none"> - Item - Case - Pallet